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10/550,102	09/21/2005	Takane Yokotagawa	053057	4675

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EXAMINER

NIEBAUER, RONALD T

ART UNIT PAPER NUMBER

1654

MAIL DATE DELIVERY MODE

09/17/2007

PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary

Application No.

10/550,102

Applicant(s)

YOKOTAGAWA ET AL.

Examiner

Ronald T. Niebauer

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 19 July 2007.
- 2a) ☒ This action is FINAL. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1,3 and 9-14 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☒ Claim(s) 1 is/are allowed.
- 6) ☒ Claim(s) 3 and 9-14 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some * c) ☐ None of:
1. ☒ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date _____
- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____
- 5) ☐ Notice of Informal Patent Application
- 6) ☐ Other: _____

DETAILED ACTION

Response to Amendments/Arguments

Applicants amendments and arguments filed 7/19/07 are acknowledged and have been fully considered. Any rejection not specifically addressed is herein withdrawn.

Claims 2,4-8 have been cancelled. In the restriction requirement (2/5/07), claim 10 was treated as a method. Due to the amendment, claim 10 reads on a polypeptide (Group I of the restriction requirement) and has been included in the current examination. Claims 1,3,9-14 are under consideration. Applicant has noted that a request for corrected filing receipt will be filed since the PCT application does not refer to a provisional application. Applicant has also submitted an English translation of the priority document.

The polypeptide consisting of SEQ ID NO:1 was found to be free of the prior art.

Claim Objections

(Necessitated by amendment) Claims 9,10 are objected to because of the following informalities: the claims depend from rejected claim 3. Further, claim 9 is dependent on cancelled claim 2,4-5. Appropriate correction is required.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

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(Necessitated by amendment) **Claims 3,9-14** are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 3 and dependent claims 9-14 are drawn to a polypeptide consisting of a particular sequence of which one or two of the amino acids thereof have been deleted, substituted, inserted, or added. It is unclear if the claims are drawn to a specific sequence (i.e. consisting of) or if the claims are drawn to a sequence with modifications possible. The phrase 'consisting of' is closed language (MPEP section 2111.03). If a polypeptide consists of an amino acid sequence it cannot, for example, have an amino acid added since that would improperly broaden the phrase 'consisting of'.

Written Description

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

(Maintained/Necessitated by amendment) **Claims 3,11-14** are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contain subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

(From previous office action) Section 2163 of the MPEP states:

The written description requirement for a claimed genus may be satisfied through sufficient description of a representative number of species..... A "representative number of species" means that the species which are adequately described are representative of the entire genus. Thus, when there is substantial variation within the genus, one must describe a sufficient variety of species to reflect the variation within the genus.

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Claim 3 is drawn to a polypeptide of which one or several of the amino acids have been deleted, substituted, inserted or added. This claim is broad in scope and since the degree of deletion/substitution/insertion is not specified nearly any polypeptide could meet this claim limitation. A few examples of modified polypeptides have been provided in the specification (such as example 3) but due to the substantial variation possible a sufficient variety of species has not been provided. Since the genus is broad and a representative number of species has not been described the written description requirement has not been met. Further it is well known in the art that modifying a protein by a deletion/substitution/insertion can alter the proteins structure and function. For example Bowie et al. teach that for certain proteins no substitutions can be made at particular positions (page 1306 column 2 line 18). Hence, the tolerance to amino acid sequence variation is often unpredictable. Since claim 3 refers to disulfide bond formation and channel inhibiting activity, a more specific description of the protein structure and modified residues would be needed to predict the effects of modifications.

(New) Applicants argue that amended claim 3 and new claims 11-14 more specifically describe the claimed invention. Applicants argue that not only SEQ ID NO:2 but SEQ ID NO:16 and 17 have inhibiting activity. Applicants argue that the examples are evidence that channel inhibiting activity is present even if one or two of the amino acid have been deleted, substituted, inserted, or added.

This argument is not found persuasive. Since the claims are drawn to SEQ ID NO:1, arguments drawn to SEQ ID NO:2 are not relevant. As cited previously, section 2163 of the MPEP states that 'when there is substantial variation within the genus, one must describe a sufficient variety of species to reflect the variation within the genus'. Claim 3 and new claims 11-14 read on substitutions. For simplicity, considering one substitution with one of the 20 natural amino acids in any position of SEQ ID NO:1 (10 amino acids in length) there would be 10^{20} possibilities. Having a second substitution or deletion, insertion, or addition further expands the genus. Hence, the genus is broad. As recited in paragraph [0096] and [0098] specific substitutions with alanine have been described. A substitution with alanine at a specific position is not descriptive of substitutions with the other amino acids nor is it descriptive of substitutions

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at any position. A substitution is not descriptive of a deletion, insertion, or addition. Since the tolerance to amino acid sequence variation is often unpredictable (see Bowie et al. cited previously), applicants argument that a specific example of a substitution is evidence of activity for a full genus is not found persuasive. For these reasons and the reasons mentioned in the previous office action the written description requirement is not met.

New Matter

(Necessitated by amendment) **Claims 3,12,14** and dependent claims 11,13 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

MPEP § 2163 states that, “[n]ew or amended claims which introduce elements or limitations which are not supported by the as-filed disclosure violate the written description requirement. See, e.g., *In re Lukach*, 442 F.2d 967, 169 USPQ 795 (CCPA 1971) (subgenus range was not supported by generic disclosure and specific example within the subgenus range); *In re Smith*, 458 F.2d 1389,1395, 173 USPQ 679, 683 (CCPA 1972) (a subgenus is not necessarily described by a genus encompassing it and a species upon which it reads).” Further, the MPEP states, “[w]hile there is no *in haec verba* requirement, newly added claim limitations must be supported in the specification through express, implicit, or inherent disclosure.”

In the instant case claims 3,12 specifically recite two amino acids having modifications. There is no literal support for substitutions of 2 amino acids. The original claims do recite the

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term 'several', but the term several does not necessarily support 2. Summarized in Figure 7, the examples do not support substitutions of 2 amino acids of SEQ ID NO:1. SEQ ID NO:1 (TVP003 in Figure 7) can have a single substitution of AARPKLKC with C to obtain TVP005. However, this is not a substitution of 2 amino acids. One would not conclude from the examples or the specification that substitution implies a substitution of 2 amino acids.

Further claim 14 specifically recites that the cysteine residues are not modified. There is no literal support for such a limitation. For SEQ ID NO:1, the example provided involves a single substitution of AARPKLKC with C to obtain TVP005. Since this involves a cysteine residue it does not provide support for the current claim limitation. One would not conclude from the examples or the specification that substitution implies a substitution except for that of a cysteine residue.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

(Maintained in part/Necessitated by amendment) **Claims 3,9-14** are rejected under 35 U.S.C. 102(b) as being anticipated by Oswald et al. (as cited in IDS).

Oswald et al. teach the GsMTx-4 peptide

GCLEFWWKCNPNDKCCRPKLKCSKLFKLCNFSSG (Figure 1) which comprises SEQ ID NO:1 (i.e.WKCNPNDKCK).

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As stated above, for purposes of examination since claims 3,9-14 imply both closed and open language, the claims will be interpreted broadly to include peptides that comprise the recited amino acid sequence. It is also noted that claim 3 does not specify the length of the deletion, substitution, insertion, or addition. When GCLEFWW is substituted for W and when CCRPKLKCSKLFKLCNFSSG is substituted for C of SEQ ID NO:1, claim 3 limitations are met with the resulting GsMTx-4 peptide. Further, when GCLEFW and CRPKLKCSKLFKLCNFSSG are added to SEQ ID NO:1, claim 3 limitations are met with the resulting GsMTx-4 peptide. Claim 14 limitations are met when GCLEFWW is substituted for W and CRPKLKCSKLFKLCNFSSG is added to obtain the GsMTx-4 peptide (i.e. the cysteine residues of SEQ ID NO:1 are not deleted, substituted, inserted, or added). Regarding claims 9 and 10, the claim preamble does not result in a structural limitation (MPEP section 2111.02) and does not serve to limit the claim.

It is noted that the amendment has overcome the rejection as it pertains to claim 1, not any other claims. It is also noted that perfecting foreign priority dates cannot be used to overcome a 102(b) rejection (MPEP section 2133.02).

Conclusion

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

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A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.


Any inquiry concerning this communication or earlier communications from the examiner should be directed to Ronald T. Niebauer whose telephone number is 571-270-3059. The examiner can normally be reached on Monday-Thursday, 7:30am-5:00pm, alt. Friday, EST.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Cecilia Tsang can be reached on 571-272-0562. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.


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PRIMARY EXAMINER